In The United States District Court
Southern District of Ohio

In re: Ohio Execution Protocol Litigation,	Case No. 2:11-cv-1016 Judge Edmund Sargus, Jr. Magistrate Judge Michael Merz

Motion to Quash Subpoena Issued to Interested Party Ohio State Board of Pharmacy

I. Introduction

The State of Ohio Board of Pharmacy ("the Board") has received a subpoena issued by Plaintiff Cleveland Jackson demanding copious amounts of documents and demanding a deposition (presumably under Civ. R. 30(B)(6), although that provision is never cited).

The Board has already provided substantial documents to Plaintiff as a professional courtesy. As the Board had promised in its earlier filing, the Board provided "electronic lists of all resident and non-resident persons and entities currently licensed as a distributor of dangerous drugs by the OSBP . . . [in an] Excel spreadsheet." *Request for Documents* #2. The Board also provided a list of all pharmacies that have reported that they engage in compounding sterile controlled substances. *Request for Documents* #3.

The subpoena is essentially asking about two subject areas: (1) licensing of terminal distributors of dangerous drugs (TDDD) and sterile compounding and (2) the Board's efforts to police against diversion of drugs.

Before going on, the Board must emphasize that its understanding of this litigation is necessarily limited. The subpoena in this case is the 2,198th document filed in the case. The cumulative page count is already above 100,000. But even with this caveat, the Board is perplexed why it is being drawn into this litigation, especially asking about how it handles investigations of opioids and benzodiazepines.

With this caveat, the Board asks that the Court quash the subpoena issued because the requests for documents are unduly burdensome, unlikely to lead to the discovery of admissible evidence and are requesting information confidential under state and federal law. The Board asks that the Court quash the subpoena for testimony regarding TDDD applications because the issues are legal, not factual. The Court should quash the subpoena for testimony regarding diversion compliance because the testimony is unlikely to lead to the discovery of admissible evidence and because the topic areas are poorly defined.

II. Compliance With Local Rule 37.1.

Under Local Rule 37.1, this Court precludes an entity from filing a motion to quash until "counsel have first exhausted among themselves all extrajudicial means for resolving the differences." The Board submits that this requirement has either been met or is inapplicable under these circumstances.

The Board (a non-party) has been given a remarkably short time frame to respond to a subpoena. The subpoena was served after business hours on April 29th. On April 30, this Court gave the Board a deadline of only 4 business days to file any motions to quash.

In addition, it appears that Plaintiff is unwilling to remove any requests from the subpoena. At the April 30th status conference, counsel for the Board raised many concerns about the subpoena. That would have been the opportunity for counsel for the Plaintiff to indicate whether the subpoena could be narrowed, clarified or adjusted to meet the Board's concerns. Instead, counsel for Plaintiff stayed silent, suggesting that Plaintiff will not agree to any compromise. (If that's not the case, counsel for the Board is willing and able to discuss potential compromises.)

Counsel for Plaintiff has not reached out since the status conference to address any of the concerns that the Board raised. Under the extraordinary circumstances placed upon a non-party with no vested interest in the outcome of this case, the Board submits that Local Rule 37.1 is either inapplicable or has been satisfied.

III. TDDD and Sterile Compounding

The Board has already provided the key documentation that it has available. It has provided a list of all TDDDs[1] licensed by the Board. The

[1] A TDDD is not synonymous with pharmacies. All licensed pharmacies must hold a TDDD license, but also includes many entities that dispense medications such as veterinarians, physicians and hospitals.

list identifies which TDDD has reported that it performs compounding. The Board has also provided a list of all entities licensed as wholesale distributors of dangerous drugs (WDDD) (i.e. entities that sell to TDDDs).

The Board *cannot* provide a comprehensive list of individual pharmacists who perform compounding because the "practice of pharmacy" in Ohio includes "compounding drugs." R.C. 4729.01(B)(3). The Board does not require pharmacists to report this information to the Board nor does compounding require a separate license to perform. This would be akin to asking the Ohio Supreme Court for a list of all attorneys licensed in Ohio who prepare wills. Anyone who is a lawyer can prepare a will, but the Ohio Supreme Court does not keep track of who actually does. The Board is in the exact same situation in regards to identifying individuals those who are performing compounding. (As noted above, that isn't the case for pharmacies, and the Board has provided relevant information as self-reported by applicants).

This should resolve any issues regarding document production required about this subject. To the extent that Plaintiff wishes to have more documents from the Board regarding TDDDs and compounding, the Court should quash those requests.

The Board specifically opposes the request for a deposition under Civ. R. 30(b)(6) regarding these areas because the issues are really legal in nature rather than factual. It is the Board's understanding that there is question

about how easy it would be for an out-of-state entity to obtain a license as a TDDD or WDDD.

Plaintiff has the information that it needs to answer that question. In addition to providing the Excel spreadsheets requested, the Board provided copies of all relevant application forms (something not specifically requested but provided as a professional courtesy).

The rest of the issues are going to be legal. The standards for obtaining a TDDD are identified in R.C. 4729.54 and 4729.55 and Ohio Adm. Code 4729-9, 4729:5-2-02(B) or Ohio Adm. Code 4729:5-8 (for a non-resident TDDD). The standards for obtaining a license to operate a WDDD are found in R.C. 4729.52 and 4729.53 and Ohio Adm. Code 4729:6-2-02.

If an entity applies and meets all requirements, it is entitled as a matter of law to receive a TDDD or a WDDD license. If the Board believes that an entity might not be eligible for a TDDD or a WDDD, it must provide that applicant with an opportunity for a hearing under R.C. Chapter 119.

Because the issues that Plaintiff wishes to address can be answered by reading a handful of provisions, there is simply no reason to hold a Civ. R. 60(B)(3) deposition to delve any further into the licensing subject area.

IV. Diversion Controls Of Controlled Substances

A. Request for Documents

Plaintiff has ordered the Board to provide "all documents, communications, or other materials relating to the above-listed Deposition

Topics." And what does Plaintiff want? "[A]ny investigation by the OSBP of a dangerous drug distributor" of any drug "that Ohio has used or could use to carry out a human execution by lethal injection." Plaintiffs define that broadly to include any opioid or benzodiazepine. The time frame? Over eight years.

Plaintiff also wants a comprehensive list of "reports of suspicious orders" submitted by drug distributors but also wants any "zero reports." (A zero report is submitted "if no suspicious orders have been identified by the distributor in a calendar month." Ohio Adm. Code 4729:6-3-05.)

Request is Overbroad and Unduly Burdensome.

It is hard to overstate how overbroad and unduly burdensome this request is. The Board investigates thousands of cases per year for diversion that may be taking place at a "dangerous drug distributor." Plaintiffs' request means that it is seeking information that includes TDDDs and WDDDs. TDDDs are broadly defined. An entity will be a TDDD if it is "engaged in the sale of dangerous drugs at retail . . . who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption." R.C. 4729.01(Q). The definition includes a non-comprehensive list: "pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist, licensed

health professional authorized to prescribe drugs, or other person authorized by the state board of pharmacy." R.C. 4729.01(Q).

If read literally, the Board would have to comb through every investigation that it has had in the last 8 years to see if the matter involves a potential diversion of opioids or benzodiazepines from a pharmacy, hospital nursing home or other TDDD. The Board would also have to review the investigative documents to determine whether it would contain any patient information. For instance, if a pharmacy technician steals pills by "shorting" a pill bottle, the Board would have to redact out any patient identifying information from the investigative file.

In reviewing a claim that a document request is unduly burdensome, this Court should consider the "the breadth of the document request, the time period covered by it, the particularity with which the documents are described and the burden imposed." *Am. Elec. Power Co. v. United States*, 191 F.R.D. 132, 136 (S.D.Ohio 1999) (citations and quotation omitted). "[T]he status of a person as a non-party is a factor that weighs against disclosure." *Id.* (citations omitted).

In this case, every one of those factors weighs against Plaintiff. The breadth is overwhelming, the time frame is nearly a decade and there is virtually no particularity in how the documents are described. Throw in the fact that the Board is a non-party and the answer is clear. Even if the

requests were more narrowly tailored, Plaintiff has to show that there is a reasonable likelihood to discover admissible evidence.

As noted above, it is difficult at best to keep up with all the twists and turns of this litigation. But with that caveat, the Board is at a loss to see how documents about drug diversion will lead to admissible evidence about whether Ohio's method of execution is unconstitutional under the Eighth Amendment.

The Board's position is that the Ohio Department of Rehabilitation and Corrections ("DRC") may obtain and use controlled substances during lethal injections because the General Assembly has authorized the use of controlled substances in lethal injection pursuant to R.C. 2949.21, R.C. 2949.22, R.C. 2949.221 and R.C. 2949.24.

If DRC uses drugs lawfully purchased from a licensed TDDD to carry out an execution then, as a matter of Ohio law, there has been no diversion. If an employee of DRC steals one or more of the medications from DRC (which appears to be Plaintiff's concern), then by definition it will not be used in an execution.

This Court should quash the request for documents about the Board's investigations and reports received from drug distributors.

Insufficient Time To Respond

Plaintiff has asked for untold numbers of documents and given thirteen business days to provide them. The reality is that the Board would

have to hire an outside contractor to perform this review and would struggle to produce this volume of information even in a year.[2]

Even if this Court orders the Board to produce documents, it is going to need to set an extensive time frame for the Board to provide them.

Investigative Materials Are Confidential

Under Ohio law, investigative materials that it obtains are confidential. R.C. 4729.23. The Board acknowledges that federal courts apply federal privilege law in determining whether Evid. R. 501 bars disclosure of information. But the fact that the General Assembly has designated investigative materials to be confidential should weigh in favor of this Court's discretionary determinations whether the requests are unduly burdensome.

Materials From The OARRS Database Are Confidential

The reports from drug distributors that Plaintiff request are filed into an OARRS database pursuant to Ohio Adm. Code 4729:8-3-01(C) and (D). Records contained within the OARRS database are subject to both state law confidentiality and several federally recognized privileges. Even if those provisions were inapplicable, however, this Court should deem information contained within the OARRS database to be privileged because of the strong federal and state interest in the confidentiality of those records.

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[2] If extensive document discovery is required, then the Board asks that the Federal Public Defender be required to bear the costs of paying for the outside contractor to perform this document production.

OARRS was created with a federal grant from the National All Schedules Prescription Electronic Reporting ("NASPER") Act of 2005. 42 U.S.C. §280g-3. In providing this grant money, Congress required states to protect the records from improper access or disclosure. Ohio has done so. *See* R.C. 4729.80 and 4729.99(J). The confidentiality and security of data is central to the operation of all prescription drug monitoring programs ("PDMP" or "PMP").

The OARRS database itself is protected by R.C. 4729.80. Information in OARRS and records of requests for access to that information are confidential and not subject to release. R.C. 4729.80(C). Further, even when information has been lawfully obtained from the database, that information may not be further disclosed or used except in very, very narrow circumstances. *See* R.C. 4729.86. OARRS records are explicitly prohibited by state law from being used in any civil or administrative proceedings. R. C. 4729.86(B). To the extent that OARRS reports have been generated as parts of investigations by various state licensing agencies, those reports are also deemed confidential by law. *See, e.g.,* R.C. 4723.28(I); 4729.23; 4731.22(F)(5).

The confidentiality of OARRS data is not simply a creature of state law, but rather the State's expression of a strong federal preference for the confidentiality of PDMP data. Ohio's confidentiality laws were adopted as a condition for federal funding, and should be treated by this Court as enjoying federal support. *See South Dakota v. Dole*, 483 U.S. 203, 206 (1987). From

the very beginning, the need to protect the security of the information to be contained in a state PDMP database was well-understood. Indeed, the Supreme Court in *Whalen* devoted an entire paragraph to explaining the security precautions taken by the State of New York in connection with its PDMP. *See Whalen*, 429 U.S. at 593-94, 601. When the federal government decided that it was in the national interest to encourage the development of state PDMPs, security of the information contained therein was an important element of those efforts. When Ohio applied for NASPER funding, the law required Ohio to pass statutes that specified not only what information should be contained within a state PDMP database, but also that use and disclosure of that information should be limited to approved individuals for proper purposes. *See* Pub. L. No. 109-60 Sec. 399O(f), (g). Specifically, NASPER required that states seeking funding develop a statutory scheme authorizing release of PDMP database information to: 1) healthcare practitioners "*for the purpose of providing medical or pharmaceutical treatment or evaluating the need for such treatment to a bona fide current patient*;" 2) law enforcement personnel only when "*related to an individual investigation or proceeding involving the unlawful diversion or misuse of a schedule II, III, or IV substance, and such information will further the purpose of the investigation or assist in the proceeding*;" 3) another state PDMP; 4) agents of certain specified federal agencies who certify "*that the requested information is necessary for research to be conducted by such*

department, program, or administration, respectively, and the intended purpose of the research is related to a function committed to such department, program, or administration by law that is not investigative in nature;" 5) state agents charged with the implementation of the PDMP database. *See* Pub. L. No. 109-60 Sec. 399O(f) (emphasis added). NASPER continues to require that materials be kept confidential. States seeking funding from HHS must enact legislation imposing penalties for the unauthorized use and disclosure of information retained within a PDMP. *See* 42 U.S.C. §280g-3(a)(2)(A).

Consistent with the requirements set by NASPER[3], the Ohio General Assembly enacted R.C. 4729.80 to restrict access to the database and information derived therefrom to certain specified classes of individuals. At present, OARRS access is granted to: 1) healthcare practitioners;[4] 2) law enforcement and Court personnel;[5] another state PDMP;[6] 3) other state agencies required to use prescription data to carry out their designated functions;[7] 4) an individual seeking their own records;[8] 5) peer review committees.[9] And, as previously noted, improper access to, or distribution of, OARRS data is a crime. As the state law confidentiality provisions applicable to OARRS are mere reflections of the federal prerogative to preserve the

[3] The provisions of R.C. 4729.80 track the requirements to receive initial grants found in NASPER. *See* Pub. L. 109-60 Sec. 399O(F).
[4] R.C. 4729.80(A)(5), (6), (12), (21); (B)(1), (2).
[5] R.C. 4729.80(A)(1), (2), (3), (4), (16), (17)
[6] R.C. 4729.80(A)(14).
[7] R.C. 4729.80(A)(8), (9), (10), (11).
[8] R.C. 4729.80(A)(7), (19).
[9] R.C. 4729.80(A)(21).

confidentiality of state PDMPs, this Court should find that Plaintiff cannot obtain the reports that drug distributors have submitted to OARRS.

B. Deposition

The Court should grant the motion to quash the subpoena for depositions on the diversion issues because, as discussed above, there is no reasonable likelihood of discovering admissible information.

Aside from that issue, Plaintiffs' topics for diversion are too broad and amorphous for an effective Civ. R. 30(b)(6) deposition. Does Plaintiff want to know about results of specific investigations? About the investigative process in general? Why specific individuals were disciplined or not disciplined? The Board cannot tell and certainly will not be able to have a witness prepared to testify about every permeation of the issues listed in the subpoena by May 16th. Keep in mind that a Civ. R. 30(b)(6) deposition is not just about an individual's knowledge, beliefs, or understanding. Whoever testifies as a Civ. R. 30(b)(6) witness will be speaking for the Board as an entity. It is not fair to the Board to submit a Civ. R. 30(b)(6) request that is so poorly focused.

This Court should quash the subpoena requiring the Board to submit a witness for deposition about topics involving diversion.

Respectfully submitted,

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Certificate of Service

A copy of the foregoing was served on all counsel by operation of this Court's electronic filing system.

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